IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 1 PLAINTIFFS LISTED ON EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF JOYE K. LOWMAN, M.D., M.P.H.

Pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and Federal Rules of Evidence 403, 702, and 703, Plaintiffs submit this Memorandum of Law in support of their Motion to Exclude the Opinions and Testimony of Dr. Joye K. Lowman.

I. Introduction and Summary

Dr. Lowman was retained by Defendants to give a large number of general opinions about the effectiveness and safety of Ethicon's Prolift System.[1] Plaintiffs move to exclude two parts of her opinions.

First, Dr. Lowman testified many studies support the use of the Prolift for high-risk patients. She concludes that this makes the product, as sold and marketed by Ethicon, reasonably safe for its intended use and not defective. Ethicon marketed the product, however, for "most patients," not just high-risk ones. Dr. Lowman's opinions about the Prolift's alleged reasonable safety, therefore, cannot be reliably applied to the facts of these cases and are inadmissible. Second, Dr.

[1] Exhibit B: Expert Report of Dr. Lowman in relation to *Patricia L. Hammons v. Ethicon Women's Health and Urology, A Division of Ethicon, Inc., et al*, used as the general expert report for *IN RE: ETHICON,INC., PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION*, MDL No. 2327, p. 3-4.

Lowman relates a story about a colleague who was crying and retired from private practice because she had a patient who died after Abdominal Sacral Colpopexy (ASC-an alternative to mesh surgery.) This testimony should be excluded because it is not based on reliable methods, is hearsay, and its probative value is outweighed by its prejudice.

Legal Standard

The proponent of expert testimony must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm–O–Disc, Inc.*, 137 F.3d 780, 783 (4th Cir.1998). Expert testimony is admissible if the expert is proven to be qualified and the testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case." FED. R. EVID. 702. Opinion evidence may be admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993).

Under Rule 702, the test of a reliable foundation looks to whether the expert's opinions are "the product of reliable principles and methods." FED. R. EVID. 702. An expert opinion must be grounded in the "methods and procedures of science," and must consist of more than "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 589. The Supreme Court describes several factors for the gatekeeper trial court to use in assessing whether the reasoning or methodology underlying expert testimony is scientifically valid and whether the reasoning or methodology properly can be applied to the facts in issue: (1) whether a theory or technique "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) a consideration of the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether there is "general

acceptance" of the theory within the relevant scientific community. *Id.* at 593-94.

Even if the expert is qualified and the testimony is reliable, "testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2:12-MD-02327, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, the testimony must "fit" both expert's qualifications and the case, *i.e.* there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id*.

II. Argument and Citation of Authority

A. Doctor Lowman's Opinion That The Prolift is Not Defective Because It Is An Accepted Alternative for High-Risk Patients Is Inadmissible Because The Prolift Was Marketed for All Patients.

In Dr. Lowman's report, she states, "there is a role for transvaginal mesh augmentation in high-risk patients."[2] Quoting the American Urogynecologic Society and the American College of Obstetricians and Gynecologists 2011 committee opinion, she explains, "Pelvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk…"[3] In her deposition, Dr. Lowman explains that the aforementioned committee opinion that she used to form her opinions concerning the Prolift, defines high-risk patients as those who have recurrence and advanced degrees of prolapse.[4] Moreover, she testified that the "Prolift is indicated in treating high-risk patients."[5] She reasoned

[2] *Id*. at 15.
[3] *Id.*
[4] Exhibit C: Deposition of Dr. Lowman, in relation to *Patricia L. Hammons v. Ethicon Women's Health and Urology, A Division of Ethicon, Inc., et al*, used as the general deposition *for IN RE: ETHICON,INC., PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION, MDL No. 2327*, November 13, 2015, p. 124.
[5] Exhibit D: Deposition of Dr. Lowman, in relation to *Patricia L. Hammons v. Ethicon Women's Health and Urology, A Division of Ethicon, Inc., et al*, used as the general deposition *for IN RE: ETHICON,INC., PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION, MDL No. 2327*, December 13, 2015, p. 91.

that since Prolift is a reasonable option for certain high-risk patients the product as sold and marketed by Ethicon is reasonably safe for its intended use and not defective.[6]

Ethicon did not, however, limit its marketing to high risk patients with reoccurrence or advanced degree prolapse. Instead it's marketing brochure stated, "Half of women over age 50 experience some degree of pelvic organ prolapse."[7] "Procedures with the GYNECARE PROLIFT are appropriate for most patients..."[8]

Dr. Lowman's testimony that Ethicon's Prolift is not defective because it is an accepted treatment option for high-risk patients is inadmissible because her testimony has not been reliably applied "to the facts of the case." FED. R. EVID. 702. She has rendered an opinion about a fictional product that was marketed solely for high-risk patients, while the Prolift was marketed for all patients.

B. Doctor Lowman's Story about a Colleague Who Cried And Then Retired from Practice after A Patient Dies from ASC Surgery Is Inadmissible Hearsay, Not Based on Reliable Methods, And Its Probative Value Is Outweighed by Its Prejudice.

In Dr. Lowman's report she laments that the Prolift is no longer an option for her patients because the procedure she uses instead, the ASC, is invasive.[9] She states, "It is difficult to describe how severe and dangerous this procedure can become to those who are not surgeons."[10] She then goes on to describe a recent encounter with a colleague who was in tears in the surgeons' locker room.[11] The colleague explained to Dr. Lowman that she had a patient recently die during an ASC procedure.[12] "She had formerly performed many vaginal mesh procedures with great success, but

[6] Expert Report of Dr. Lowman, p. 15; Deposition of Dr. Lowman, December 13, 2015, p. 66.
[7] Exhibit E: Ethicon Women's Health and Urology Brochure, "Pelvic Organ Prolapse: Get the Facts, Be Informed, Make YOUR Best Decision," p. 3.
[8] *Id.* at p. 13.
[9] Dr. Lowman's Expert Report at 18.
[10] *Id.*
[11] *Id.*
[12] *Id.* at 19.

had moved to doing ASC with robotic assistance after the FDA PHN in 2011."[13] The colleague was so devastated that she sold her practice and retired from clinical practice.[14]

This emotional testimony is not based on reliable scientific principles or methods and, therefore, is not helpful and is inadmissible. *Daubert*, 509 U.S. 579, 593-94. It is also inadmissible hearsay and its probative value it outweighed by its prejudice. FED. R. EVID. 403, 703 (Concerning expert testimony, FED. R. EVID. 703 explains, "if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.")

III. Conclusion

For the forgoing reasons, Dr. Lowman's proposed testimony and opinions outlined above are inadmissible and should be excluded.

Dated: April 21, 2016

By: *s/Fidelma L. Fitzpatrick*
Fidelma L. Fitzpatrick
Motley Rice LLC
321 South Main Street
Providence, RI 02903
Phone: (401) 457-7700
Fax: (401) 457-7708
jorent@motleyrice.com
ffitzpatrick@motleyrice.com

Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esq.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102

[13] *Id.*
[14] *Id.*

Fax 816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com

CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

s/Fidelma Fitzpatrick
Fidelma L. Fitzpatrick
Motley Rice LLC
321 South Main Street
Providence, RI 02903
Phone: (401) 457-7700
Fax: (401) 457-7708
ffitzpatrick@motleyrice.com